

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 135.11, 139A.19, 139A.35, 141A.3, 141A.4, 141A.6, 141A.7, 141A.10, and 915.40 to 915.43, the Iowa Department of Public Health hereby gives Notice of Intended Action to amend Chapter 11, “Human Immunodeficiency Virus (HIV) Infection and Acquired Immune Deficiency Syndrome (AIDS),” Iowa Administrative Code.

The rules in Chapter 11 describe procedures and programs related to HIV/AIDS, including testing and reporting requirements, HIV-related training programs, notification and testing of exposed persons, and the AIDS drug assistance program (ADAP). These proposed amendments respond to previous changes to the Iowa Code that removed the state requirement for two hours of HIV-related training for emergency and nonemergency personnel and that altered language relating to the release of HIV-related test results under a court order. In addition, these amendments add definitions of “meningococcal disease” and “tuberculosis” to clarify the terms as they are used in 2014 Iowa Acts, Senate File 2297, which amended Iowa Code chapter 709D. The amendments also change the term “transplant center” to “organ procurement organization” in the definition of “health facility” and clarify the HIV-reporting requirements for these organizations. Testing requirements for pregnant women are also clarified. Finally, eligibility requirements for the two component programs within ADAP are made identical at less than or equal to 400 percent of the federal poverty level, and the assessment of income for ADAP enrollees is simplified by removing the requirement to calculate modified adjusted gross income. Costs for the additional participants will be covered by 340B Drug-Pricing Program rebates that ADAP receives directly from pharmaceutical manufacturers for people enrolled in the Insurance Assistance Program component of ADAP.

Any interested person may make written comments or suggestions on the proposed amendments on or before December 13, 2016. Such written comments should be directed to Randy Mayer, Bureau of HIV, STD and Hepatitis, Department of Public Health, 321 East 12th Street, Des Moines, Iowa 50319. E-mail may be sent to randall.mayer@idph.iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 135.11, 139A.19, 139A.35, 141A.3, 141A.4, 141A.6, 141A.7, 141A.10, and 915.40 to 915.43.

The following amendments are proposed.

ITEM 1. Amend rule **641—11.1(139A,141A)**, definitions of “Director of a plasma center, blood bank, clinical laboratory, or public health laboratory” and “Health facility,” as follows:

“*Director of a plasma center, blood bank, clinical laboratory, organ procurement organization, or public health laboratory*” means the person responsible for direction and operation of the facility, the medical director, or the person designated by the director or medical director to ensure compliance with applicable regulations and requirements.

“*Health facility*” means a hospital, health care facility, clinic, blood bank, blood center, sperm bank, laboratory organ ~~transplant center~~ and procurement agency organization, or other health care institution.

ITEM 2. Amend subrule 11.4(1) as follows:

11.4(1) ~~All pregnant women, including minors, shall be tested for HIV infection as part of the routine panel of prenatal tests. Health care providers that offer prenatal care to women shall provide HIV testing to all pregnant women, including minors, as part of the routine panel of prenatal tests. The health care provider requesting the HIV test of a pregnant woman shall notify a the pregnant woman that HIV~~

screening is recommended for all prenatal patients and that the pregnant woman will receive an HIV test as part of the routine panel of prenatal tests unless the pregnant woman objects to the test. No written or oral consent shall be required.

ITEM 3. Amend subrule 11.6(2) as follows:

11.6(2) Within seven days of the receipt of a person's confirmed positive test result indicating HIV infection, the director of a plasma center, blood bank, organ procurement organization, clinical laboratory or public health laboratory that performed the test or that requested the confirmatory test shall make a report to the department on a form provided by the department.

ITEM 4. Amend subrule 11.7(1) as follows:

11.7(1) A director of a plasma center, blood bank, organ procurement organization, clinical laboratory or public health laboratory or a physician or other health care provider who repeatedly fails to file the report required pursuant to these rules is subject to a report being made to the licensing board governing the professional activities of the individual. The department shall notify the individual each time the department determines that the individual has failed to file a required report. The department shall inform the individual in the notification that the individual may provide information to the department to explain or dispute the failure to report.

ITEM 5. Amend rule 641—11.11(135) as follows:

641—11.11(135) Purpose. The purpose of this rule is to describe the required content of HIV and AIDS training programs and to identify the groups of personnel involved.

11.11(1) ~~Nonemergency personnel.~~ Before an initial assignment of tasks where occupational exposure to blood or other potentially infectious materials may take place and at least annually thereafter, all supervisory and patient care personnel of any agency listed below shall complete a minimum of two hours of training concerning AIDS-related conditions and the prevention of HIV infection training concerning blood-borne pathogens, including human immunodeficiency virus and viral hepatitis, consistent with standards from the Occupational Safety and Health Administration of the U.S. Department of Labor:

- a. A licensed hospice,
- b. A homemaker-home health aide provider agency which receives state homemaker-home health aide funds, or
- c. An agency which provides respite care services ~~and receives state funds for respite care services.~~

11.11(2) ~~Content~~ Nonemergency personnel training content. Training programs must address the following topics:

- a. ~~HIV disease processes~~ Symptoms and modes of transmission of blood-borne diseases,
- b. ~~Signs and symptoms~~ Location and handling of personal protective equipment,
- c. ~~Transmission;~~ Information on the hepatitis B vaccine, and
- d. ~~High-risk activities;~~ Follow-up procedures in the event of an exposure.
- e. ~~Prevention recommendations, and~~
- f. ~~Standard precautions as defined by the CDC and the Occupational Safety and Health Administration of the U.S. Department of Labor.~~

11.11(3) ~~Emergency and law enforcement personnel.~~ All Before an initial assignment of tasks where occupational exposure to blood or other potentially infectious materials may take place and at least annually thereafter, all emergency medical services personnel, firefighters, and law enforcement personnel shall complete a minimum of two hours of training concerning AIDS-related conditions and the prevention of HIV infection training concerning blood-borne pathogens, including human immunodeficiency virus and viral hepatitis, consistent with standards from the Occupational Safety and Health Administration of the U.S. Department of Labor.

11.11(4) ~~Content~~ Emergency and law enforcement personnel training content. Training programs must address the following topics:

- a. ~~HIV disease processes~~ Symptoms and modes of transmission of blood-borne diseases,
- b. ~~Signs and symptoms~~ Location and handling of personal protective equipment,

- c. ~~Transmission, Information on the hepatitis B vaccine, and~~
- d. ~~High-risk activities, Follow-up procedures in the event of an exposure.~~
- e. ~~Prevention recommendations, and~~
- f. ~~Standard precautions as defined by the CDC and the Occupational Safety and Health Administration of the U.S. Department of Labor.~~

This rule is intended to implement Iowa Code section 135.11.

ITEM 6. Adopt the following new definitions of “Meningococcal disease” and “Tuberculosis” in rule **641—11.22(139A)**:

“*Meningococcal disease*” means acute infectious bacterial meningococcal infection presenting as invasive disease characterized by one or more clinical syndromes including bacteremia, sepsis, or meningitis. It does not include nasopharyngeal colonization by *Neisseria meningitidis*.

“*Tuberculosis*” means infectious tuberculosis as defined in 641—1.1(139A).

ITEM 7. Amend subrules 11.34(5) and 11.34(6) as follows:

11.34(5) Results of a test performed under 641—11.30(915) to 641—11.34(915), except as provided in subrule 11.34(6), shall be disclosed only to the physician or other practitioner who ordered the test of the convicted or alleged offender; the convicted or alleged offender; the victim; the victim counselor or person requested by the victim who is authorized to provide the counseling regarding the HIV-related test and results; the physician of the victim if requested by the victim; the parent, guardian, or custodian of the victim, if the victim is a minor; and the county attorney who filed the petition for the HIV-related testing under 641—11.30(915) to 641—11.34(915), ~~who may use the results to file charges of criminal transmission of HIV~~. Results of a test performed under these rules shall not be disclosed to any other person without the written informed consent of the convicted or alleged offender. A person to whom the results of a test have been disclosed under 641—11.30(915) to 641—11.34(915) is subject to the confidentiality provision of Iowa Code section 141A.9, and shall not disclose the results to another person except as authorized by Iowa Code section 141A.9.

11.34(6) If HIV-related testing is ordered under 641—11.30(915) to 641—11.34(915), the court shall also order periodic testing of the convicted offender during the period of incarceration, probation, or parole or of the alleged offender during a period of six months following the initial test if the physician or other practitioner who ordered the initial test of the convicted or alleged offender certifies that, based upon prevailing scientific opinion regarding the maximum period during which the results of an HIV-related test may be negative for a person after being HIV-infected, additional testing is necessary to determine whether the convicted or alleged offender was HIV-infected at the time the sexual assault or alleged sexual assault was perpetrated. The results of the subsequent periodic tests conducted pursuant to subrule 11.34(6) shall be released only to the physician or other practitioner who ordered the test of the convicted or alleged offender; the convicted or alleged offender; the victim counselor or person requested by the victim to provide the counseling regarding the HIV-related test and results, who shall disclose the results to the petitioner; the physician of the victim if requested by the victim; and the county attorney, ~~who may use the results as evidence in the prosecution of the sexual assault or in the prosecution of the offense of criminal transmission of HIV~~ who filed the petition for the HIV-related testing under 641—11.30(915) to 641—11.34(915).

ITEM 8. Rescind the definition of “Modified adjusted gross income” in rule **641—11.40(141A)**.

ITEM 9. Amend rule 641—11.43(141A) as follows:

641—11.43(141A) Eligibility requirements.

11.43(1) An applicant is eligible to participate in the ADAP medication assistance program if the applicant:

- a. Applies for enrollment in ADAP on a form provided by the department;
- b. Has no health insurance to cover the cost of the drugs that are or may become available from ADAP;
- c. Is currently being prescribed a drug on the ADAP formulary;

d. Has an annual MAGI income that is less than or equal to ~~200~~ 400 percent of the poverty level as determined by the most recent federal poverty guidelines published annually by the U.S. Department of Health and Human Services for the size of the household (~~this income shall be determined after a \$500 work-related allowance is deducted from the monthly salary of an employed person with HIV/AIDS~~);

e. Has a medical diagnosis of HIV infection or AIDS or is an unborn infant or an infant under 18 months of age who has an HIV-infected mother; and

f. Is a resident of Iowa.

11.43(2) An applicant is eligible to participate in the ADAP health insurance assistance program if the applicant:

a. Applies for enrollment in ADAP on a form provided by the department;

b. Has creditable health insurance coverage;

c. Is currently being prescribed a drug on the ADAP formulary;

d. Has an annual MAGI income that is less than or equal to 400 percent of the poverty level as determined by the most recent federal poverty guidelines published annually by the U.S. Department of Health and Human Services for the size of the household;

e. Has a medical diagnosis of HIV infection or AIDS or is an unborn infant or an infant under 18 months of age who has an HIV-infected mother; and

f. Is a resident of Iowa.

ITEM 10. Amend paragraph **11.45(1)“c”** as follows:

c. The enrolled individual’s annual MAGI income increases to an amount above the respective ADAP component’s income guidelines;